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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,940	06/15/2006	Toru Moriguchi	292106US0PCT	9811

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EXAMINER	
ML, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
05/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/582,940	MORIGUCHI ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-18 and 26-42* is/are pending in the application.

4a) Of the above claim(s) *34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-18,26-33 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/11/09 has been entered.

Applicant's amendment in the reply filed on 3/11/09 is acknowledged, with the cancellation of Claims 1-15, and 19-25; and the additional newly added Claims 37-42. Claims 16-18, and 26-42 are pending. Claim 34-36 are withdrawn from consideration as being directed to a non-elected invention. **Claims 16-18, 26-33, and 37-42 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Objections

Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 recites "The food or beverage according to claim 29, wherein the food or beverage is attached with a label indicating that the food or beverage improves central function, visual acuity or circulatory function". It is noted that whatever is

on the label is not going to further limit the food or beverage. A food is a food, the function of the food is determined by its components, but by its label.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 27, 30, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites "The composition according to claim 16, wherein the composition further comprises one or more compounds selected from the group consisting of ginseng, Panax notoginseng, Siberian ginseng, arginine, Ginkgo biloba, soybean, carnitine, bilberry, blueberry, raspberry, rutin, cassis, citric acid, sesame, sprouted sesame, rutin, garlic, onion, fermented soybeans, Echinacea, black cohosh, vitamin C, vitamin E, catechin, astaxanthin, sesamin and polyphenols". The recitation of clam 26 is very confusing as ginseng, Panax notoginseng, Siberian ginseng, Ginkgo biloba, soybean, bilberry, blueberry, raspberry, sesame, sprouted sesame, garlic, onion, fermented soybeans, Echinacea, black cohosh, are plant materials, not compounds. For the same reason, the rejection applies to claim 27 as well.

Claims 30 and 33 recite the limitation "the form" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is not clear what "form" Applicant is referring to.

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-18, 28-33, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al (JP 07017855 A), in view of Noble et al (US 5,484,611).

Kimura et al teach a cerebral function-improving composition comprises one kind or more of n-3 series fatty acids consisting of docosahexaenoic acid, eicosapentaenoic acid and α-linolenic acid as an active ingredient and one kind or more of lipolipids selected from the phosphatidyl choline (PC), phosphatidyl ethanolamine (PE), phosphatidyl serine (PS), phosphatidyl inositol (PI) or their liso compounds. Kimura et al teach the composition is useful for the prevention and treatment of senile dementia, and having a good cerebral function-improving effect (see Abstract). Kimura et al also teach the composition in the form of a functional food (thus a solid) (page 2, claim 1 in full translation), and a medication in the form of a powder, granules, tablets, sugar-coated pills, capsules, pills, liquid formulations, etc. Examples of diluent are an excipient, binder, moisturizing agent, disintegrator, surface active agent,

lubricant, dispersing agent, buffer, taste modifier, deodorizer, fragrance, preservative, solubilizing assistant, and solution etc (page 20, [0023] in full translation).

Kimura et al do not teach the incorporation of a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of decosahexaenoic acid, or the ratio of linolenic acid to the phospholipid.

Noble et al teach docosahexaenoic acid linked with phospholipid (claim 1), wherein the docosahexaenoic acid linked with the phospholipid is made into the form of tablets (thus contains a pharmaceutically acceptable carrier) (a solid), capsules, powder or solution (a liquid) (claim 6). Noble et al also teach a method of a method of treatment of an animal body, comprising administering to the body a composition in biocompatible form which contains docosahexaenoic acid-linked phospholipids wherein said phospholipids are phosphatidyl ethanolamine, phosphatidyl serine, phosphatidyl choline, and phosphatidyl inositol (claims 1 and 9). Noble et al teach that the DHA-phospholipid is effective for treating degenerative disease of brain and nervous system caused by aging (col 4, lines 23-30).

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the docosahexaenoic acid linked with the phospholipid from Noble et al since Noble et al teach the DHA-phospholipid is effective for treating degenerative disease of brain and nervous system. Therefore, one of the ordinary skill in the art would have been motivated to add the DHA-phospholipid into the composition of Kimura et al to enhance the treatment efficacy of senile dementia, and improve the cerebral function.

Since both of the compositions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications to combine the

teachings of the references together. Regarding the limitation to the ratio between linolenic acid and phospholipid, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft

Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the ratio between linolenic acid and phospholipid, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have the ability treat degenerative disease of brain and nervous system caused by aging, which would have been routinely determined and optimized in the pharmaceutical art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 16-18, 26-33, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al and Noble et al as applied to claims 16-18, 28-33, and 37-42 above, and further in view of Kanowski et al (Kanowski et al, Proof of efficacy of the Ginkgo biloba special extract EGb 761 in outpatients suffering mild to moderate primary degenerative dementia of the Alzheimer type or multi-infarct dementia, Pharmacopsychiat 29 (1996) 47-56).

The teachings of Kimura et al and Noble et al are set forth above and applied as before.

The combination of Kimura et al and Noble et al do not specifically teach the incorporation of Ginkgo biloba into the composition.

Kanowski et al teach the efficacy of the ginkgo biloba special extract EGb 761 in outpatients with presenile and senile primary degenerative dementia of the Alzheimer-type (DAT) and multi-infarct dementia (MID) according to DSM-III-R was investigated in a prospective, randomized, double-bind, placebo-controlled, multi-center study. The clinical efficacy of the ginkgo biloba special extract EGb 761 in dementia of the Alzheimer type and multi-infarct dementia was confirmed (see Abstract).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use *Gingko biloba* from Kanowski et al into the composition of Kimura et al since Kanowski et al teach ginkgo biloba special extract EGb 761 is effective in treating dementia of the Alzheimer type and multi-infarct dementia. Therefore, one of the ordinary skills in the art would add *Gingko biloba* extract to the composition of Kimura et al to enhance the treatment efficacy of senile dementia, and improve the cerebral function. Since all of the compositions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kimura et al and Kanowski et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655